Contains Nonbinding Recommendations

Draft Guidance on Balsalazide Disodium

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Balsalazide Disodium

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 1.1 g (dose = 3×1.1 g)
   Subjects: Healthy males and nonpregnant females, general population.
   Additional comments: Applicants may consider using a reference-scaled average bioequivalence approach for this drug product. If using this approach, the applicant should provide evidence of high variability in the bioequivalence parameters (i.e., within-subject variability $\geq$ 30%) for the reference product. For general information on this approach refer to the Progesterone Capsule Guidance for additional information regarding highly variable drugs.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in-vivo
   Strength: 1.1 g (dose = 3×1.1 g)
   Subjects: Healthy males and nonpregnant females, general population.
   Additional comments: see above

Analytes to measure (in appropriate biological fluid): Balsalazide and Mesalamine in plasma

Bioequivalence based on (90% CI): Balsalazide and Mesalamine

Waiver request of in vivo testing: Not Applicable

In vitro dissolution testing under the following conditions should be submitted to support documentation of bioequivalence:

Strength:	1.1 g
Apparatus:	USP Apparatus 2 (paddle)
Medium:	0.1N HCl at 50 rpm and 100 rpm
	pH 4.5 buffer at 50 rpm and 100 rpm
	pH 6.8 buffer at 50 rpm and 100 rpm
	pH 7.4 buffer at 50 rpm and 100 rpm

Volume: 1000 mL
Temperature: 37ºC
Additional comments: The applicant should use at least 12 tablets per test. The f2 metric will be used to compare dissolution profiles.

Dissolution test method and sampling times:
Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.